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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,033	03/31/2000	Richard G. Miller	35828-0079	3667

21839 7590 02/20/2002

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/541,033	Applicant(s) MILLER ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/7/01 (Paper No. 14), is acknowledged. Claim 6 has been amended.

Claims 1-11 are pending and are under consideration in the instant application with respect to the species elected without traverse in Paper No.8.

2. Applicant's provision of full citations for IDS references "Genetic Engineering News" and "Chen YL, Eur. J. Pharmacol." is acknowledged. The corrected IDS, filed 12/7/01 has been initialed accordingly and the incomplete duplicate citations crossed off the original IDS filed 8/3/00.

3. Applicant's substitute specification and claims, filed 12/7/01 in permanent ink, are acknowledged. The amendment filed concurrently on 12/7/01 has been entered into the substitute specification and claims.

4. Applicant's statement that corrected Formal Drawing will be submitted in a supplementary reply is acknowledged. However, correction of drawings may no longer be held in abeyance.
Please see the form PTO-948 previously supplied as part of Paper No. 9.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

5. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 12/7/01 (Paper No. 14). The rejections of record can be found in the previous Office Action (Paper No. 9).

6. Applicant's amendment, filed 12/7/01, has obviated the previous rejection of claim 6 under 35 U.S.C. 112, second paragraph.

7. Claims 1-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bolton (US Pat. No. 5,980,954, IDS) in view of Jacobs et al (US Pat. No. 5,605,690, of record).

Applicant's arguments, filed 12/7/01, have been fully considered but have not been found convincing for the reasons of record in Paper No. 9.

Applicant reviews the requirements for a *prima facie* case of obviousness and asserts that the references relied upon do not provide either a motivation or a reasonable expectation of success with respect to combining the therapies taught by each reference.

As noted previously, the claims are drawn to a method of treating a subject suffering from rheumatoid arthritis by administering the therapeutic treatment of p75 TNFR:Fc and autologous blood exposed to an oxidative environment, electromagnetic emission, and a temperature above body temperature.

Jacobs et al. teach and claim a method of lowering the levels of active TNF-α in a mammal having arthritis by administering a TNF antagonist, including TNFR:Fc (see entire document, especially claims and Examples 4-6). Jacobs et al. further teach the specific therapeutic treatment comprising TNFR:Fc p75 TNFR:Fc (e.g., Examples 1 and 2 in conjunction with columns 2-3 "Definitions").

Contrary to Applicant's assertion that Jacobs does not teach combination therapies, as previously noted Jacobs et al. further teach that a combination therapy of TNFR:Fc and another composition that also mediates a partial reduction in arthritis symptoms (rmu IL-1R) resulted in greater reduction of arthritis symptoms than did administration of either composition alone (see especially Example 4 at columns 17-18).

The Examiner again acknowledges that Jacobs et al. do not teach co-administering autologous blood exposed to an oxidative environment, electromagnetic emission, and a temperature above body temperature.

However, Bolton et al. teach and claim a method of treating a subject suffering from rheumatoid arthritis by administering autologous blood exposed to an oxidative environment, electromagnetic emission (i.e., UV radiation), and a temperature above body temperature (see entire document, especially claims and Abstract). Electromagnetic emission is taught via a specific embodiment, UV radiation (e.g., claim 6-7 and column 8). Bolton et al. also teach that this method can be generally applied to a variety of autoimmune and inflammatory conditions, specifically including multiple sclerosis, scleroderma, diabetes, inflammatory bowel disease, psoriasis, atherosclerosis, and organ rejection (see especially column 9 at lines 29-40).

Given the teachings of the references that rheumatoid arthritis could be treated by administering either TNFR:Fc or autologous blood exposed to an oxidative environment, electromagnetic emission (UV radiation), and a temperature above body temperature; it would have been obvious to the ordinary artisan at the time the invention was made to combine the two treatments.

The ordinary artisan would have been motivated by the teachings of Jacobs et al. that combination therapy is advantageous to use these two treatments in the form of a combination therapy. Given that each treatment works individually, the ordinary artisan would have had a reasonable expectation of success with respect to the combination therapy.

Applicant is reminded that it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Further, the ordinary artisan at the time the invention was made would have recognized that the therapeutic treatment (i.e., TNFR:Fc) and modified blood could have been administered either simultaneously or consecutively while still functioning as a synergistic combination. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejection is therefore maintained.

8. No claim allowed

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
February 19, 2002

Phillip Gambel
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PRIMARY EXAMINER
TECH CENTER 1600
2/19/02